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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,822	10/13/2006	Yung-chi Cheng	Y03-097US Nat	8995

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COLEMAN SUDOL SAPONE, P.C.
714 COLORADO AVENUE
BRIDGE PORT, CT 06605-1601

EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,822	CHENG ET AL.	
	Examiner	Art Unit	
	Brian-Yong S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-36 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-39 and 44-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/19/06, 10/16/06, 09/29/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner for the instant application has changed. The current examiner assigned to this application is Brian-Yong S. Kwon.

Applicants Response to Restriction Requirement Acknowledged

2. Applicant's election with the Group VI Invention along with a singe species where "R5 is methyl, R6 is propyl, R7 is propyl and R8 is H" is acknowledged.

Applicants traverse the restriction requirement on the grounds that all of the claimed compounds are structural analogs of the central pharmacophore having a phenyl group appended thereto. Applicant alleges that all of claimed compounds have an identical nucleus and a common utility (enhancing bioavailability), which provides a unity of invention.

This argument is not persuasive, as claimed invention would be distinctive, each from the other because the common technical feature linking all groups, the baicalein derivatives represented by the formula is known in the prior art (e.g., USP 6025387; WO 2003/015737). Therefore, Groups I -VI do not share special technical feature with each another. As such, unity between the above Groups I-VI is broken.

Furthermore, the species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because they are distinct species which may have different chemical or physical properties. For instance, 5-hydroxy-6,7-dimethoxy flavone or 5,7-dihydroxy-6-methoxy flavone encompassed by the instant formula is known to be useful for the treatment of ulcer and inflammatory conditions, respectively.

Furthermore, the search of the entire groups in the non-patent literature (a significant part of a thorough examination) would be burdensome. Therefore, the requirement is still deemed proper, and made Final. Claims 1-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.

It is noted that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The applicant's elected species where "R5 is methyl, R6 is propyl, R7 is propyl and R8 is H" appears to be allowable over the prior art. Thus, the examiner will extend the search to other non-elected species represented by the formula where "R5 is H, R6 is methyl, R7 and R8 are H" and examine for prosecution on the merits of the case. Claims 37-39 and 44-48 read on the elected species. In addition above mentioned withdrawn claims 1-36, claims 40-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims.

Information Disclosure Statement

3. Enclosed is an initialed copy of PTO 1449 which has been considered for your records.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 37-39 and 44-48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential step(s), such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step(s) is/are: a step of administering to particular patient population, e.g., "a host", "a subject" or "a patient".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 37-39, 44-46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US 6806257).

Lee teaches an administration of flavone derivative such as oroxylin A (5,7-dihydroxy-6-methoxy flavone) alone or in combination with antibiotics (e.g., pencillin, cephalosporin, vancomycin, etc…) for the treatment of sepsis, aneurysm, inflammation and related pathology (abstract; column 9, line 25 through column 10, line 20; column 17, line 56 through column 18, line 56; claims).

Although Lee is silent about the activity of said oroxylin A in "facilitating or enhancing the bioavailability of another bioactive agent or drug" and "said bioactive agent attains a level which is at least twice the level attained in the absence of said enhancing agent" recited in claims 37 and 46, respectively, such feature or characteristic deems to be inherent to the reference method when the same compound represented by the formula such as oroxylin A is co-administered with antibiotics to a patient. It is noted that the prior art directing the administration of same compound possessing inherent therapeutic effect for the same ultimate purpose as disclosed by the applicant anticipates the instant invention even absent recitation of the underlying mechanism.

As discussed above, the instantly claimed property is "deliberate or necessary consequence" when oroxylin A is administered to a patient as taught by the reference along with other active such as antibiotics. Thus, Lee anticipates the claimed invention.

With respect to "said bioactive agent or drug acts on the central nervous system" and "said bioactive agent acts on the brain" recited in claims 44 and 45, respectively, the examiner determines that such feature or characteristics deems to be inherent to the antibiotics, for example vancomycin (see attached Luer et al., The Annals of Pharmacotherapy, abstract, Vol. 27, No. 7, pp.912-921 for your reference). It is noted that

products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

6. Claims 37-39 and 44-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheu et al. (USP 6793944)

Sheu teaches an administration of a composition comprising an extract of scutellaria containing oroxylin A (5,7-dihydroxy-6-methoxy flavone) in combination with extract of ginseng, rhubarb and/or ginger for the treatment of various disease conditions associated with iNOS activity and COX-2 activity including hypertension, coronary heart disease, cerebrovascular disease, stroke, cancer, etc…(abstract; "Background of the Invention"; column 4, line 50 through column 5, line 10; Table 1).

Although the prior art is silent about the activity of said compound in "facilitating or enhancing the bioavailability of another bioactive agent or drug" and "said bioactive agent attains a level which is at least twice the level attained in the absence of said enhancing agent" recited in claims 37 and 46, respectively, such feature or characteristic deems to be inherent to the reference method when a composition containing oroxylin A is co-administered with ginseng containing herbal composition to a patient.. It is noted that the prior art directing the administration of same compound possessing inherent

therapeutic effect for the same ultimate purpose as disclosed by the applicant anticipates the instant invention even absent recitation of the underlying mechanism.

With respect to “an antitumor or anticancer agent” recited in claim 47, given "broadest reasonable interpretation", the examiner determines that ginseng which has been known to have anticancer effect (see USP 6888014; US PG Pub 20080050426; WO 97/31933 for your references) falls within "metes and bounds" of the instant invention.

Conclusion

7. No Claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For

more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614